UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Date: February 9, 2006

Subject: Efficacy Review for Environ San
EPA Reg. No. 1677-185
DP Barcode: 323865;

From: Lorilyn M. Montford
Efficacy Evaluation Team
Antimicrobials Division (7510C)

Through: Nancy Whyte, Acting Team Leader
Efficacy Evaluation Team
Antimicrobials Division (7510C)

To: Marshall Swindell, PM 33/Karen Leavy
Regulatory Management Branch I
Antimicrobials Division (7510C)

Applicant: ECOLAB, Inc.
370 N. Wabasha Street
St. Paul, MN 55102

Formulation:

Active Ingredient(s)	% by wt.
Hydrogen Peroxide	11.2%
Peroxyacetic Acid	15.2%
Inert Ingredients	73.6%
Total	100.000%

I BACKGROUND

The product, Enviro San, acid sanitizer, (EPA Reg. No. 1677-185), is an EPA approved, commercial food contact sanitizer for use on hard, non-porous surfaces in dairies, dairy barns, restaurants, food service operations, breweries, wineries, beverage and food processing plants. The applicant has requested an amendment to include directions for commercial sterilization of food packaging materials and equipment. Ecolab initially cited a 6 month storage stability data study for marketing reasons, which increased the lower certified limits. This change allows for 1 year stability. The dosage ranges for existing claims on the label have been increased to account for the change in lower certified limits. Studies were conducted at Ecolab, Inc. located at 655 Lone Oak Drive, Eagan, MN 55121.

II USE DIRECTIONS

The product is designed to be used for sanitizing tableware, utensils, dishes, equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in restaurants, food service operations, dairies, breweries, wineries, beverage and food processing plants. General Cleaning instructions provide the following instructions: "Prior to sanitizing, remove gross food particles, wash with a detergent solution, followed by a potable water rinse. Sanitize with a concentration of 0.10 – 0.18% v/v [volume of ENVIRO SAN to volume of dilution water]" For sanitizing eating, drinking and food prep utensils the following is provided: "Remove gross food particles by a pre-scrape, pre-flush and when necessary, a presoak treatment; wash with a recommended detergent; rinse with clean water; sanitize in a solution of 0.10 to 0.18% v/v (1000 to 1800 ppm v/v or 1 to 1.8 ounces per 8 gallons [peroxyacetic acid weight to dilution water weight].

III COMMENTS ON THE SUBMITTED EFFICACY STUDY

1. MRID 466745-01 "Commercial Sterilant Efficacy Of Enviro San At 3.4 Oz Per Gallon With Es-1000 Adjuvant. Study conducted at Ecolab, Inc. by Laurinda Holen. Study completion date – October 17, 2005. Study Number 0500021.

This study was conducted against *Clostridium sporogenes* (ATCC 3584), *Bacillus subtilis* (ATCC 19659) and *Bacillus cereus* (ATCC 14579). Three lots of the product, Enviro San (DJR205A, DJR605A and DJR605B), and adjuvant, ES-1000 (DJR205C, DJR505A, and DJR505B) were tested. This study requires 60 carriers for each test system on each of three batches of Enviro San and three batches of ES -1000, one of each of which is at least 60 days old. Each polished stainless steal penicillin cup carriers were inoculated with the prepared culture suspension at a ratio of 1 mL per carrier. Carriers were allowed to soak in the suspension for >20 minutes at room temperature. After soaking, the prepared culture was aspirated off and the carriers were aseptically transferred to sterile Petri dishes matted with 2 layers of Whatman No. 2 filter paper. The carriers were placed on the Petri dishes on end in a vertical position so that the carriers did

not touch each other. The Petri dishes were covered and placed into a desicator containing $CaCl_2$ dessicant. Following the drying period, each carrier was aseptically transferred to individual tubes containing 10mL of the test substance utilizing sterile wire hooks. After the 19 second exposure period, carriers were subcultured into individual tubes of the Fluid Thioglycollate with 0.5% Sodium Thiosulfate. After all the transfers were complete, each carrier was transferred to a secondary subculture tube of Fluid Thioglycollate with 0.5% Sodium Thiosulfate.

IV RESULTS

Pre Heat-Shock					
Test Date	**Date Results Read**	**Test System**	**Test Substance Batch # /Adjuvant#**	**#1° Tubes Showing No Growth of Test System/#Total Tubes**	**#2° Tubes Showing No Growth of Test System/#Total Tubes**
9/2/05	9/23/05	*Clostridium sporogenes*	DJR205/DJR205C	60/60	60/60
			DJR605A/DJR505A	60/60	60/60
			DJR605B/DJR505B	60/60	60/60

Post Heat-Shock					
Test Date	**Date Results Read**	**Test System**	**Test Substance Batch # /Adjuvant#**	**#1° Tubes Showing No Growth of Test System/#Total Tubes**	**#2° Tubes Showing No Growth of Test System/#Total Tubes**
9/2/05	9/26/05	*Clostridium sporogenes*	DJR205/DJR205C	60/60	60/60
			DJR605A/DJR505A	60/60	60/60
			DJR605B/DJR505B	60/60	60/60

Pre Heat-Shock					
Test Date	**Date Results Read**	**Test System**	**Test Substance Batch # /Adjuvant#**	**#1° Tubes Showing No Growth of Test System/#Total Tubes**	**#2° Tubes Showing No Growth of Test System/#Total Tubes**
9/14/05	10/05/05	*Bacillus cereus*	DJR205/DJR205C	60/60	60/60
			DJR605A/DJR505A	60/60	60/60
			DJR605B/DJR505B	60/60	60/60

Post Heat-Shock					
Test Date	**Date Results Read**	**Test System**	**Test Substance Batch # /Adjuvant#**	**#1° Tubes Showing No Growth of Test System/#Total Tubes**	**#2° Tubes Showing No Growth of Test System/#Total Tubes**
9/14/05	10/08/05	*Bacillus cereus*	DJR205/DJR205C	60/60	60/60
			DJR605A/DJR505A	60/60	60/60
			DJR605B/DJR505B	60/60	60/60

Pre Heat-Shock					
Test Date	Date Results Read	Test System	Test Substance Batch # /Adjuvant#	#1° Tubes Showing No Growth of Test System/#Total Tubes	#2° Tubes Showing No Growth of Test System/#Total Tubes
9/16/05	10/7/05	*Bacillus subtilis*	DJR205/DJR205C	60/60	60/60
			DJR605A/DJR505A	60/60	60/60
			DJR605B/DJR505B	60/60	60/60

Post Heat-Shock					
Test Date	Date Results Read	Test System	Test Substance Batch # /Adjuvant#	#1° Tubes Showing No Growth of Test System/#Total Tubes	#2° Tubes Showing No Growth of Test System/#Total Tubes
9/16/05	10/10/05	*Bacillus subtilis*	DJR205/DJR205C	60/60	60/60
			DJR605A/DJR505A	60/60	60/60
			DJR605B/DJR505B	60/60	60/60

Enumeration of Test System

Test Date	Date Results Read	Test System	Replicate	CFU/mL	Average CFU/Carrier
9/2/05	9/5/05	*Clostridium sporogenes*	1	3.4×10^5	5.1×10^5
			2	3.4×10^5	
			3	8.6×10^5	

Test Date	Date Results Read	Test System	Replicate	CFU/mL	Average CFU/Carrier
9/14/05	9/19/05	*Bacillus cereus*	1	1.3×10^5	1.0×10^5
			2	1.1×10^5	
			3	7.4×10^5	

Test Date	Date Results Read	Test System	Replicate	CFU/mL	Average CFU/Carrier
9/16/05	9/19/05	*Bacillus subtilis*	1	6.4×10^5	5.3×10^5
			2	3.6×10^5	
			3	5.8×10^5	

Enumeration of all test systems demonstrated a survivor population of $>10^4$ CFU/Carrier after the drying step.

V CONCLUSIONS

1. The submitted efficacy data support the use of the product, Enviro San with ES-1000, as a sanitizer as a commercial sterilant for food packaging materials against the following microorganism on hard, non-porous surfaces for a contact time of 19 seconds.

   Clostridium sporogenes (ATCC 3584) MRID No. 466745-01

Bacillus cereus (ATCC 14579)	MRID No. 466745-01
Bacillus subtilis (ATCC 19659)	MRID No. 466745-01

VI RECOMMENDATIONS

1. The proposed label claims that the product, Enviro San is an effective sanitizer on hard, non-porous surfaces against the following for a contact time of 19 seconds, are acceptable.

   Clostridium sporogenes
   Bacillus cereus
   Bacillus subtilis

Data provided by the applicant support these claims.